EXHIBIT I

Medical Devices

Questions and Answers About the Baxter Colleague Recall, Refund, and Replacement Action

Updated September 3, 2010

What does this action entail?

The FDA sent a letter to Baxter on April 30, 2010, ordering the company to recall and destroy ALL MODELS of its Colleague Volumetric Infusion Pumps (Colleague pumps) currently in use in the United States. The FDA believes there may be as many as 200,000 of the pumps currently in use.

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Where can I view a copy of the Final Order to Baxter?

The Final Order is posted on the FDA web site at
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm218753.htm [1]

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When will the Recall, Refund, and Replacement program start and when will it end?

The program began on the July 13, 2010 and the transition period will end July 14, 2012. Baxter's Transition Guide will

contain the specific details regarding the program.

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What should hospitals and other Colleague pump users do now?

Clinicians and home-care users may continue to use Colleague pumps during the transition period, but the FDA recommends replacement of Colleague infusion pumps as soon as practicable. Baxter will provide a Transition Guide no later than September 14, 2010 to help customers through the transition and installation of a new infusion pump system.

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What is the Colleague Pump Transition Guide that Baxter will be issuing no later than September 14, 2010?

The Transition Guide will include the following information:

- Detailed information on the refund and replacement programs.
- Instructions on how to complete the Certificate of Medical Necessity, which must be returned promptly in order to continue receiving support and be eligible for the replacement/refund.
- An accurate and complete list of the currently known risks associated with the continued use of the Colleague infusion pumps, including all open recalls and deficiencies known to Baxter at the time the Transition Guide is distributed.
- Suitable FDA approved or cleared alternatives to the Colleague infusion pumps, and their respective manufacturers.
- Ways to minimize disruption and reduce risk to patients during the transition period.
- The need to have appropriate training for staff prior to using alternative infusion pumps.
- The need to verify and validate the alternative pumps prior to use within the healthcare facility.
- A list of consultants who can assist facilities with the verification and validation of the alternative infusion pumps prior to use.

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How much will the refund be?

If you own Baxter pumps:

Colleague owners will be able to obtain a cash refund to purchase an FDA-cleared pump they choose, or to receive a replacement pump from Baxter at no charge. The refund will be the depreciated value of the pump or the owner's documented purchase price, whichever is less. All refunds are to be issued within 10 days after Baxter receives the returned pumps.

The depreciated value will be based on the purchase price of the pump. The Final Order stops depreciation at June 29, 2006, the date FDA issued the Consent Decree prohibiting further sales of the Colleague in the US. The minimum depreciated pump value is $1,500 for a single channel Colleague pump or $3,000 for a triple channel Colleague pump. The Final Order provides a formula with an example for calculating the depreciated value of the Colleague.

Colleague triple channel owners will have the option to receive a combination of a cash refund and/or replacement for all three channels. For example, one may choose to replace one or two of the channels with single channel pumps and accept a cash refund for the remaining channel(s).

If you have unused Colleague pump spare parts, batteries, and consumables:

The order requires Baxter to provide a full refund for the return of all unused Colleague pump spare parts, batteries, and consumables in unbroken packaging that are not past their shelf-lives. In addition, Baxter will refund all maintenance contract holders for the unused portion of any Colleague infusion pump service contract within 10 days after receipt of the unit by Baxter.

The Transition Guide to be issued by Baxter no later than September 14, 2010 will provide further information.

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If I own a triple-channel pump, will all three channels be refunded or replaced?

The Order requires Baxter to provide a channel-for-channel refund, replacement, or combination of refund and replacement for each channel.

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If I purchased my Colleague from a company other than Baxter, what am I entitled to?

All Colleague owners who can provide proof of purchase price are entitled to a refund from Baxter.

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If I lease my Colleague pumps from Baxter, will I receive a refund?

All lessees of Colleague pumps who lease their pumps from Baxter can terminate their leases without penalty and can obtain a refund from Baxter for the unused portion of any Colleague infusion pump lease within 10 days of receipt of the Colleague pump by Baxter.

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If I lease/rent my Colleague pumps from a third party, will I receive a refund?

Because the Colleague pumps are considered by FDA to be adulterated and misbranded, FDA expects third party firms who lease the pumps to healthcare providers to return them to Baxter and make any necessary arrangements with their lessees.

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How do I get my cash refund or new pump from Baxter?

All owners who intend to use their Colleague pumps during the transition period and wish to be eligible for the cash refund or replacement MUST complete and return the certificate of Medical Necessity (CN). The replace, return, and refund processes will be detailed in the Transition Guide. All refunds are to be issued within 10 days after Baxter receives the returned pumps.

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How long will facilities have to transition to new pumps?

Healthcare facilities and other pump owners will have until July 14, 2012 to transition to new replacement infusion pumps.

Baxter will continue to support Colleague customers including servicing and maintaining the pumps, until the facility has transitioned to a new pump or until July 14, 2012

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If I have a bundled purchase agreement with Baxter, will I be penalized for changing the parts of that agreement that rely on Baxter Colleague usage?

Baxter will not enforce any contract shortfall/minimum purchase penalties due to the transition to an infusion pump where Baxter products cannot be used by that pump. A change in a facility's pricing tier to reflect the new purchasing level based on a customer's reduced purchase of Baxter products does not constitute a contract shortfall/minimum purchase penalty.

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How will FDA monitor the recall?

FDA oversees each recall to make sure that the actions Baxter takes are adequate to protect the public health. During the recall, FDA will ensure that Baxter files a bi-monthly report, which will include information such as the number of pumps that have been returned; the number and dollar amounts of refunds issued; the number of Colleague pumps replaced with alternative pumps, and any other information that will show Baxter's compliance with FDA's order.

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How did FDA account for healthcare provider input in crafting the Final Order?

FDA's goal in the negotiation of the Final Order was to protect the public health by removing a product with numerous deficiencies from the market while minimizing disruption to health care facilities, preventing a shortage of infusion pumps, and allowing health care facilities to maintain their current level of service to patients.

FDA sought feedback from healthcare facilities about the logistical and financial challenges of the Colleague recall. FDA also asked facilities of different sizes about the time needed to smoothly transition to new pumps, and considered the time infusion pump manufacturers will need to meet the demand for new pumps. Based on that information, FDA and Baxter agreed on a two-year timeframe for the recall and refund or replacement program.

In setting the requirements of the Final Order, FDA wanted to make sure that healthcare facilities would be able to maintain the same level of care after transitioning to new pumps. Therefore the order provides that facilities can receive a refund of up to 90% of the purchase price, as well as the option of a combination of a channel-for-channel exchange and a

cash refund for Colleague triple channel pumps. The refund will help assure that healthcare facilities have the resources to transition to alternate FDA-approved or cleared infusion pumps.

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What should health care providers and other users of Baxter's Colleague pumps do to mitigate the risks associated with the pumps?

- Review all recalls for your Colleague pumps. For information on problems with the Colleague pumps and actions to address these problems, see the Baxter Colleague Safety Information page [3].[4] Notify all clinicians about this recall and provide information and/or training regarding the issue.
- See the overall strategies for health care professionals and other users of these pumps that FDA has developed. For general risk reduction strategies for users of infusion pumps, go to: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202498.htm [5].
- Have a back-up plan in case an infusion pump fails. This plan should detail:
  - How to obtain a working back-up infusion pump and infusion tubing quickly when caring for high-acuity patients, even in transport situations.
  - How to handle high-risk infusions when the infusion pump fails. This may include staying with and closely monitoring the patient while another staff member obtains a working infusion pump.
  - How to handle infusions when the infusion pump fails in vulnerable patient populations (e.g., individuals sensitive to fluid overload). This may include clamping and disconnecting the infusion tubing from the patient to prevent over-infusion prior to obtaining a new infusion pump.

In the Transition Guide, Baxter will provide information on all known issues associated with Colleague pumps so that health care facilities and clinicians can mitigate the risk to patients while using a Colleague pump until they receive a replacement pump.

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Why is the FDA requiring Baxter to take this Recall, Refund, and Replacement Action now?

The number and severity of recalls and reports of serious adverse events associated with the Colleague pump led the agency to take this action. Prior to FDA's order, Baxter had proposed that corrections of longstanding problems with its Colleague pumps would not be complete until 2013. In view of the fact that problems with the pumps can lead to delay or interruption of critical therapies and put patients at risk, the FDA believes this to be an unacceptable timeframe that would present an unreasonable risk to public health.

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What actions has FDA taken in the past regarding the Colleague pumps?

The FDA has worked actively since 1999 to identify and correct problems with the Colleague pump, while being mindful of concerns about the medical necessity of infusion pumps, the availability of replacement units, and the financial burden to user facilities of obtaining replacement units.

The FDA took a number of actions regarding Colleague pumps, including:

- The seizure of Colleague pumps in October 2005, due to numerous deficiencies in Baxter's compliance with the quality system regulation and numerous defects with the Colleague infusion pumps.
- A June 2006 consent decree, which required Baxter to bring its operations and the distributed Colleague pumps into compliance with FDA regulations. As required by the consent decree, Baxter has not sold Colleague pumps in the United States since 2006.
- Seven Class I recalls, from 2005 through 2009, for problems including software and hardware defects and battery failures.
- Numerous meetings between the FDA and Baxter.

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How many Colleague pumps are in distribution?

The FDA believes there may be as many as 200,000 Baxter Colleague pumps currently in distribution. This includes approximately 50,000 triple channel pumps and 150,000 single channel pumps.

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Is there an alternative device ready as a replacement?

There are many legally marketed infusion pumps that are currently available for sale in the U.S. Baxter's Transition Guide will provide information on alternative pumps.

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What about other infusion pumps? Are patients at risk?

Overall, the benefits of infusion pumps outweigh their risks:

- Infusion pumps have contributed to improvements in patient care, allowing for a greater level of control, accuracy, and precision in drug delivery, thereby reducing medication errors.
- The alternatives, manual infusion or gravity drip, have their own risks and benefits.
- In most situations, using an infusion pump is viewed as the standard of care and the safest route of delivering fluid into a patient's body in a controlled manner.
- To address safety concerns with infusion pumps generally, the FDA recently announced a new infusion pump initiative, which can be found at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htm [6].

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When and how do I report problems with infusion pumps?

Report any infusion pump problem that results in an adverse event. An adverse event can include any undesirable experience associated with the use of the pump on a patient such as death, a life-threatening event, hospitalization or prolonged hospitalization, disability, or the need for intervention to prevent permanent impairment or damage. For more information on reporting and what information to include when reporting a problem with a pump, see Reporting Problems with Infusion Pumps [7] on FDA's Infusion Pumps [8] web site.

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We encourage your feedback on this information and would welcome your suggestions for additional information you would like to see.

- Email DSMICA

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